MINUTES OF THE PUBLIC HEALTH COUNCIL

MEETING OF DECEMBER 15, 2010

MASSACHUSETTS DEPARTMENT OF PUBLIC HEALTH

PUBLIC HEALTH COUNCIL

A regular meeting of the Massachusetts Department of Public Health's Public Health Council (M.G.L. c17, §§ 1,3) was held on December 15, 2010, 9:08 a.m., at the Massachusetts Department of Public Health, 250 Washington Street, Boston, Massachusetts in the Henry I. Bowditch Public Health Council Room. Members present were: Chair, Mr. John Auerbach, Commissioner, Department of Public Health, Mr. Harold Cox, Dr. John Cunningham, Mr. Paul Lanzikos, Mr. Denis Leary, Mr. José Rafael Rivera, Dr. Meredith Rosenthal (arrived at 9:10 a.m.), Mr. Albert Sherman, Dr. Michael Wong, Dr. Alan Woodward, and Dr. Barry Zuckerman arrived at 9:13 a.m. Absent members were: Ms. Helen Caulton-Harris, Dr. Michéle David, Dr. Muriel Gillick, and Ms. Lucilia Prates Ramos. Also in attendance was Attorney Donna Levin, General Counsel.

Chair Auerbach announced that notices of the meeting had been filed with the Secretary of the Commonwealth and the Executive Office of Administration and Finance. He summarized the agenda of the day.

RECORD OF THE PUBLIC HEALTH COUNCIL MEETING OF OCTOBER 13, 2010:

Dr. Alan Woodward moved approval of the minutes of October 13, 2010. After consideration, upon motion made and duly seconded, it was voted unanimously [Drs. Rosenthal and Zuckerman not present to vote] to approve the Minutes of October 13, 2010 as presented.

PROPOSED REGULATION: INFORMATIONAL BRIEFING ON PROPOSED NEW REGULATION TO 105 CMR 129.000, HEALTH INSURANCE OPEN ENROLLMENT WAIVERS:

Note: For the record, Dr. Meredith Rosenthal, arrived at the meeting at approximately 9: 10 a.m., just as Attorney Carol

Balulescu came to the table to present 105 CMR 129.000. Dr. Barry Zuckerman arrived a few minutes later during Mr. Kevin Beagan's presentation.

Attorney Carol Balulescu, Director, Office of Patient Protection and Deputy General Counsel, accompanied by Kevin Beagan, Deputy Commissioner for the Health Care Access Bureau within the Division of Insurance presented information on a new regulation to 105 CMR 129.000, Health Insurance Open Enrollment Waivers. Please see verbatim transcript for full discussion. Attorney Balulescu stated in part, "...We are going to talk about a proposed new regulation, a new task that was assigned to the Office of Patient Protection around health insurance open enrollment waivers. Mr. Beagan will give us some background on non-group health insurance in general because it is not something that we dealt with prior to this time at the Office of Patient Protection. He will give some background on open enrollment and the statutory changes that led-up to the drafting of this regulation."

Mr. Kevin Beagan provided some background information on health insurance markets in Massachusetts and how they have changed over the last year and also the reasons why the Department of Public Health is considering a regulatory change. Mr. Beagan explained that as of 1996, individuals and small employers were allowed to buy health insurance on a guaranteed issue basis, without any pre-existing condition limitation beyond six months without any medical underwriting based upon health. He further noted that as part of the Massachusetts Health Care Reforms of 2006, a decision was made to merge the Individual (non-group) and small business health insurance markets together to reduce the cost for the individual market by about 15% per individual. There was a small increase of about 1% to 1.5% to the small employer market. This lead to lower rates for individuals in Massachusetts. However, since the carriers were eliminating pre-existing condition limitations, the Division of Insurance realized that individuals would buy health insurance only when they needed it for expensive services and then discontinue the coverage after they received the needed services. In order to alleviate this problem, the Legislature, in Chapter 288 of the Acts of

August 10, 2010, added provisions that did not allow for enrollment any time of the year but created a statutory open enrollment period for the year 2011 for January 1 to February and then July 1 through August 15th. For every year following 2011, the enrollment period will be July 1 to August 15th.

Attorney Balulescu further explained, "Chapter 288 created this new open enrollment process, but it also establishes a waiver process for persons who are seeking insurance outside the open enrollment period for whatever reason...We previously had not had anything to do with insurance enrollment issues...One thing to note is that open enrollment waivers are really a narrow subset of eligibility. The Division of Insurance will still have primary responsibility for open enrollment and regulation of health plan practices. The Health Insurance Connector will still serve as the Primary Enrollment Center for people looking for insurance who are not eligible for a group plan..."

It was noted that joint public hearings were held on the changes from Chapter 288 including the open enrollment waiver in which they had two comments. The comments came from Health Care for All and Blue Cross Blue Shield and their suggestions were incorporated into the draft open waiver regulations. Definitions and terms from the Division of Insurance and the Health Care Connector also were incorporated into the regulations. Chapter 288 originally had set an effective date of October 1 for the new provision; the Governor signed into law with the supplemental budget a brief postponement of the law with an effective date of December 1, 2010... People have to wait until January 1, 2011 through February 15, 2011 to enroll in health insurance so technically the waiver process will become available February 16, 2011.

Attorney Balulescu noted, "... the open enrollment process applies to individuals, non-group health insurance members. It doesn't apply to self-employed individuals. It is what is referred to as Commonwealth Choice that is the non-group health insurance. These rules don't apply to Commonwealth Care, the subsidized health plan that is offered through the Connector or the state MassHealth. Folks who

are eligible for the state subsidized plans can continue to enroll at any time. It does not apply to Medicare supplemental plans or other supplemental plans out in the market. They have their own enrollment rules. Examples of those eligible to apply for an open enrollment waiver: an individual that works for an employer who does not provide health insurance; or a young adult who is between jobs; those looking for non-group health insurance."

Attorney Balulescu noted the following at the Public Health Council meeting and staff's memorandum dated December 15, 2010 explains further, "...The Office of Patient Protection is to review an enrollment waiver request pursuant to a process that is set forth in regulation, with the starting point being that an applicant for a waiver must meet the definition of an eligible individual and must not have intentionally foregone coverage when the applicant was eligible to enroll in a health plan. Additionally, OPP considered the following in drafting the regulation:

- Individuals have been on notice of the mandate to carry health insurance since the law was enacted in 2006.
- If an individual has willfully gone without coverage, he or she must wait until open enrollment in order to obtain coverage.
- Any standard, objective criteria that would always enable an individual to enroll outside of open enrollment should be contained within DOI guidance. In other words, if every person in a certain situation is eligible to enroll outside of open enrollment, then it is a waste of resources on the part of the applicant, the health plan and OPP to require a waiver. DOI will provide the necessary regulatory guidance to direct insurers to enroll such individuals following review of an application, without need for a waiver. This means that the waiver process will be a case-by-case review, for individuals who do not meet clearly defined criteria, without objective criteria to guide OPP.
- Because the open enrollment requirement was adopted in order to address the problem of individuals enrolling only when they needed coverage, the individual's health status or need for coverage should not be a factor in assessing the request. This will ensure that individuals are neither granted nor denied waivers

based on the presence or absence of illness or need for insurance..."

Staff's memorandum further clarified that "Eligible individuals who miss open enrollment can still apply to health insurers for coverage...DOI guidance and the proposed OPP regulation require that the application be the first step in the process. The insurers or their agents will have to review the application and make a determination regarding the eligibility of the individual and whether the individual meets the criteria for enrollment outside of open enrollment. If the individual is not eligible to apply for non-group health insurance at all, the insurer will so advise the individual without any reference to the waiver process. If the individual is in fact eligible to enroll immediately, the health insurer will process the application. If the individual is not eligible to enroll outside of open enrollment but could request a waiver, the health insurer must direct the individual to the waiver process and include the waiver application form. If an individual's application has been denied, he or she must then submit a waiver request to OPP within 30 days of receiving the denial. Please note that because OPP will have 30 days in which to review a waiver request and respond there is a window immediately preceding open enrollment during which no waiver applications will be accepted. The regulation sets out the criteria by which OPP will assess the waiver request, which as noted will be on a case-by-case basis, with consideration given to the similarity of the individual's circumstances to those that would permit enrollment outside of the open enrollment period. The regulation also sets out requirements for insurers and their agents to provide contact information so that OPP can resolve issues with plans or refer applicants if necessary."

In closing, Attorney Balulescu noted that the waiver process is not an adjudicatory hearing and there is no further right of appeal at DPH. A public hearing is scheduled for January 10, 2011 on these proposed regulations; and she thanked the Division of Insurance for their assistance to DPH on this regulation.

Discussion followed by the Council. Please see the verbatim transcript for full discussion. During discussion, Mr. Beagan noted, "...We need to have clear rules, clear information and clear ways that consumers can get information. We did find that OPP was getting misdirected calls over the last month, and our goal is to make sure that the calls go to the right individuals and that we are able to get the right answers...to make sure that any questions are answered quickly and clearly so consumers and the Members of the Council can understand how the law is being applied..."

It was noted that Blue Cross administers a program (Medical Security Program) for those collecting unemployment insurance and that the organization Health Care for All is a wonderful resource for consumers on the various health insurance programs available and in understanding the eligibility rules and can help people get enrolled in the right program.

Dr. Wong raised the issue around people with insurance not seeking needed health care due to deductibles and co-payments that they can't afford to pay. Dr. Zuckerman spoke about people going to the emergency room for care that is covered but then not having the $25.00 to $40.00 for the prescription. Dr. Zuckerman suggested documenting these gaps as a first step to think about solutions. Chair Auerbach responded, "I think it is useful for us to document the outcomes that result from financial barriers which prevent people from seeking certain types of care...and where we can document that obstacles result in more expensive care later and poor outcomes, that can be a compelling argument for the insurers who are looking at the issues from financial perspective out of necessity because they have to have premiums that are affordable..." Mr. Beagan noted that beginning in 2011 and 2012 the Division of Insurance will be collecting information to look at utilization based upon the different levels of co-payments....It is all tied back to the cost of insurance premiums and the cost of health care." Chair Auerbach noted that when the Department conducts their yearly random telephone surveys to the residents of Massachusetts, we ask have you sought health care services in the last twelve months and were there financial obstacles to the receipt of those services that made them

unaffordable to you. Two thirds of the currently uninsured answered yes; money was an obstacle to my receiving care. For those with insurance (28%) said money was an obstacle to receiving care; the 28% probably reflecting the co-pay and deductible.

It was noted that somebody who moved to Massachusetts from another country with national insurance or from another state and could not continue coverage because the plan was not subject to COBRA may be eligible for a waiver. Anyone who had previous health care coverage and had no reason to enroll during open enrollment, like someone getting out of prison and someone discharged from the military may get a waiver. Carriers will issue a denial notice that will indicate if the individual qualifies for a waiver or not. Anybody who voluntarily terminates their insurance by non-payment is not qualified for a waiver. One can obtain a non-affordability waiver at the Health Care Connector so they don't have to pay the tax penalty. If person with this non-affordability waiver gets a job and can then afford insurance they may be eligible for a waiver. It was noted that this waiver process belongs in the Health Connector program, the enrollment people not here at DPH. Dr. Cunningham asked that the 'no further appeal' aspect of the regulation be reconsidered. Chair Auerbach noted that this concerned can be addressed at the public hearing for comment. The regulation will return to the Council for action, after the public hearing process.

NO VOTE/INFORMATION ONLY

<u>REQUEST FOR APPROVAL FOR FINAL PROMULGATION OF AMENDMENTS TO 105 CMR 650.000, HAZARDOUS SUBSTANCES REGARDING REGULATORY ACTION ON BISPHENOL-A:</u>

Mr. Geoff Wilkinson, Senior Policy Advisor, Commissioner's Office, accompanied by Attorney James Ballin, Deputy General Counsel, Office of the General Counsel presented the amendments to 105 CMR 650.000. Some excerpts from the presentation follow. Please see the verbatim transcript for the full presentation and discussion.

Mr. Wilkinson noted that the regulations ban baby bottles and non-spill (sippy cups) containing BPA for use by children under three years of age and brings the state regulation into conformity with federal definition of toxic, especially with concern to urea formaldehyde foam insulation.

He noted the concerns about the health impact from BPA exposure: "Particularly for young children, infants, and developing fetuses BPA is considered an endocrine system disrupter. It mimics the properties of estrogen and it has been linked with a number of possible health effects, especially in young children and infants. Recent science has confirmed that food is, by far, the most significant exposure route. There are other exposure routes, but BPA leeches, even at room temperature from polycarbonate bottles, plastic baby bottles, and its leeching properties increase dramatically with exposure to heat. It has been associated with problems with brain and behavioral abnormalities, reproductive effects, increased risks of prostate and breast cancer, increased rates of chromosomal abnormalities, thyroid hormone function, metabolic disorders, and other conditions."

Mr. Wilkinson noted that two public hearings were held, one in Boston on June 22nd and one in Northampton on June 23rd. Sixty-five people testified, 51 in favor, qualified support because they didn't think regulations go far enough and 14 opposed entirely to the ban. He explained the arguments for and against the regulations and noted the relevant studies around BPA. He noted other states and countries with various BPA bans.

He stated, "The bottom line is that there is not certainty about those low dose impacts, but there are literally hundreds of studies, many of them funded by NIH and academic centers that were discounted from the EFSA review...The scientific rigor of those studies with NIH approved designs was sufficiently compelling to us to want to emphasize to you that we think that the jury is still out, but the preponderance of evidence suggests that the scope of this proposed ban is warranted and that it meets the test of balancing the various

interests that are coming before us, which is our responsibility as a public agency and one that is trying to do science-based approach to this."

Mr. Wilkinson said further, "...At this stage, FDA supports reasonable steps to reduce exposure of infants to BPA in the food supply. They are supporting industry actions to stop producing BPA containing bottles and infant feeding cups, supporting developments of alternatives to BPA for the lining of infant formula cans, and they are conducting additional research."

In summary, Mr. Wilkinson stated, "The current science clearly supports a precautionary action and scope of the ban as written. Infants, young children and developing fetuses are most at risk. It is clear that migration from baby bottles presents the primary exposure route, and that there are concerns about low dose effects, acknowledge by U.S. and International regulators, U.S. states and international regulatory bodies. This proposed scope is consistent with BPA bans that have been adopted in other states and nations. It is an appropriately balanced approach, given the interests and concerns that stakeholders are raising. We can't identify any adverse economic impacts from the proposed ban since the market is already taking action, and we propose to expand the implementation date for manufacturers so that retailers can get current inventories off their shelves...The delayed implementation date seemed warranted to us, seemed like a reasonable accommodation, and this scope, as I mentioned, provides flexibility for future consideration...It will involve phased compliance applying to manufacturers, manufacturing of BPA baby bottles as of April 1 and there are no manufacturing of BPA-containing baby bottles in Massachusetts, and it would apply to retailers for July 1, 2011. It is subject to the repurchasing provisions in existing regulations. If a consumer purchased a baby bottle with BPA they are eligible for reimbursement from the retailer."

Attorney James Ballin, added, "...This proposed ban is being done pursuant to Chapter 94B of the Mass. General Laws, it essentially allows the Commissioner to ban as a hazardous substance in order to protect public health and safety, if the product cannot be adequately

labeled, and since these are products for children, there is no way to label them as not safe for children. He noted two house-keeping changes to the regulations, not related to BPA. The first change is related to the definition of toxic, part of the definition on chronic toxicity was inadvertently omitted when these regulations were originally drafted, and so we are adding the full definition back in to be consistent with the Federal Hazardous Substances Regulations. The other change is to remove language on urea formaldehyde foamed-in-place insulation (UFFI), which is no longer relevant. There were no comments on these two changes.

Discussion followed by the Council, please see verbatim transcript for full discussion. Council Member Barry Zuckerman asked for clarification on costs not being the driving issue for opposition to the regulations. Mr. Wilkinson responded, "The primary arguments have not been founded on money with respect to the proposed ban. I think the concerns about the cascade effect ultimately have a financial basis, that if there was a cascade effect, that there would be serious financial implications. For instance, to a large manufacturer in Western Massachusetts that produces polycarbonate pellets…I think you are right nobody has been able to point out for us any direct economic impact of the scope of the proposed ban. However, there are deep financial concerns that arise from the fear that this action if it undermines the public confidence in BPA, that it will be a slippery slope and will undermine markets in the future for BPA products…It is more a concern about the potential economic impact in the future with other products, that we might choose to regulate." Dr. Zuckerman further asked about the formula container studies. Mr. Wilkinson stated, "As I understand it, the focus of research-related packaging for infant formula and baby food has to do with the safety of alternative linings to BPA, and there are a number of alternative chemicals that can be used to line the lids of baby food jars and the insides of infant liquid formula cans."

Discussion continued and Mr. Josè Rafael Rivera asked, "You mentioned the fact that there was a concern about people with limited English proficiency having access to the information, can you talk about how that is going to be addressed? If I am an individual

that already has these products, how do I find out that they are not safe for my baby to be using especially when many of these families may be reusing these products for the next set of kids?" Mr. Wilkinson replied in part, "...I think we would have to look at our resources to communicate that information in different languages. If the Council approves this, we will look at that." Dr. Alan Woodward noted his concern about pregnant women and their fetuses being exposed to BPA. Mr. Wilkinson responded that was part of the argument to ban sport bottles. He said further regulation in that area is not supported by the science.

Dr. Woodward said further, "I would suggest that what you propose seems like a logical step at this point. I don't know if it is a logical first step or a logical end step, but I would ask that you keep us informed...every few months...on what is coming out relative to this and whether there should be further action or whether there is anything justified...I think the documentation you have sent is very comprehensive and complete and we are trying to investigate something where there is a lot of conflicting information at this point. He noted that it would be ideal for the FDA to have a national policy on this instead of a state by state initiative."

Council Member Paul Lanzikos said in part, "I am prepared to support the proposed regulations, but with one concern relative to your recommendation of the extension of the implementation dates to April 1 for manufacturing and July 1 for retail sale....I think there could be a disparate exposure to low income individuals because of the nature of the retail environment..." He noted that New York's retail ban will go into effect in December of 2010 and asked "What would prevent New York retailers from dumping their product in Massachusetts for the next six months? Why shouldn't we pass the regulations with the original proposed dates?" Mr. Wilkinson replied that the original proposed dates were January 1 for manufacturers and July 1 for retailers and what they are proposing now is to move back by three months the manufacturers' date so the Department can give adequate notice for business interests and in addition staff needs time to develop an action plan. He reiterated that there are no baby-bottle manufacturers in Massachusetts and very little if any in

the United States. The baby bottles come from abroad. Council Member Harold Cox asked "Who was responsible for overseeing the implementation of this regulation, the Department or is it an unfunded mandate on the local boards of health?" Mr. Wilkinson responded that the implementation in terms of enforcement will be the DPH Bureau of Environmental Health in cooperation with the Commissioner's Office, not the local boards of health.

Discussion continued and Council Member Dr. John Cunningham asked about children's plates and bowls that may get microwaved since heat exacerbates this. Mr. Wilkinson noted that including plates and bowls at this point wouldn't be practical for enforcement at this point because it is hard to distinguish what plate is intended for use exclusively by and for children under three years of age and that staff would prefer to wait for the outcome of the FDA studies to provide some stronger basis for expanded scope or not of the regulations. Dr. Cunningham responded, "Perhaps this is more of a consumer education step." Mr. Wilkinson replied, "Yes."

Chair Auerbach asked for a vote to put on the table Mr. Lanzikos' suggestion that there be an amendment to the manufacturing implementation date. Dr. Michael Wong moved to accept a motion to put Mr. Lanzikos request on the table. After being duly seconded, it was voted unanimously to approve that motion.

Mr. Lanzikos made a motion to change the manufacturing implementation date from March 1st to January 1, 2011. After consideration, upon motion made and duly seconded, it was voted unanimously to approve Mr. Lanzikos motion to change the manufacturing implementation date back to the originally proposed date of January 1, 2011.

After the above vote was taken, Deputy General Counsel, James Ballin noted that the earliest these regulations could be filed with the Secretary of the Commonwealth is December 24, 2010 which would mean an implementation date of January 7, 2011.

A third motion was made, by Mr. Lanzikos, to change the manufacturing implementation date to January 7, 2011 from March 1, 2011 instead of January 1, 2011. After consideration, upon motion made and duly seconded, it was voted: Chair Auerbach, Mr. Cox, Dr. Cunningham, Mr. Lanzikos, Mr. Leary, Dr. Rosenthal, Mr. Sherman, Dr. Wong and Dr. Woodward and Dr. Zuckerman in favor; Mr. Josè Rafael Rivera abstained [Ms. Caulton-Harris, Dr. David, Dr. Gillick and Ms. Prates Ramos absent] to approve a January 7, 2011 manufacturing implementation date instead of March 1, 2011 or January 1, 2011.

It was noted that testing for BPA takes place in a laboratory for analysis and that certification is provided by the manufacturer and retailer.

Mr. Sherman made a motion to approve staff's recommendation with Mr. Lanzikos' amendment. After consideration upon motion made and duly seconded, it was voted to approve Final Promulgation of Amendments to 105 CMR 650.000, Hazardous Substances Regarding Regulatory Action on Bisphenol-A with the amendment to change the manufacturing implementation date to January 7, 2011. A copy of the regulations presented the Council is attached and made a part of this record as Exhibit No. 14,965.

DETERMINATION OF NEED PROGRAM:

CATEGORY 1 APPLICATION: PROJECT APPLICATION NO. 3-4937 OF EYE INSTITUTE OF THE MERRIMACK VALLEY, INC.:

Mr. Jere Page, Senior Program Analyst, accompanied by Ms. Joan Gorga, Director, Determination of Need Program presented Project No. 3-4937 to the Council. Mr. Page stated in part, "The application before the Council was filed for transfer of ownership of individual licensure of the Eye Institute of the Merrimack Valley, Incorporated, a physician-owned Massachusetts corporation and is a single specialty ambulatory surgery center for ocular surgery located in Lawrence...The Eye Institute will be transferred to Boston Laser

Surgery, LLC. Specifically the proposed transaction will allow Boston Laser Surgery to acquire one hundred percent of The Eye Institute's assets at an aggregate price of $500,000. Following the transaction, The Eye Institute will be operated as Boston Laser Surgery Center, and will continue to provide the same ocular surgeries that are currently being provided at the site. Based on review of the application, Staff has determined that the applicant satisfies the four standards set forth under DoN Regulations for a change of ownership for an ambulatory surgery center found under 105 CMR 100.602 of the Determination of Need Regulations." Please see the staff summary for more detail on this application, dated December 15, 2010. Samir Melki, MD, PhD, representing the applicant was in attendance.

After consideration, upon motion made and duly seconded, it was voted unanimously to approve Project Application No. 3-4937 of The Eye Institute of the Merrimack Valley, Inc. for Transfer of ownership of The Eye Institute of the Merrimack Valley, Inc., Lawrence, MA, a single specialty (ocular surgery) ambulatory surgery center to Boston Laser Surgery Center, LLC, based on staff findings. The staff summary is attached and made a part of this record as Exhibit No. 14,966.

CATEGORY 2 APPLICATION: PROJECT APPLICATION NO. 3-3B93 of FS COMMONWEALTH, LLC, D/B/A NEW ENGLAND REHABILITATION HOSPITAL: Replacement and relocation of a 22-bed satellite unit currently located at 22 Pawtucket Street, Lowell, MA to 981 Varnum Avenue, Lowell, MA:

Note: Attorney Donna Levin, Deputy General Counsel for the Department of Public Health stepped down for this item due to a conflict of interest. Attorney Howard Saxner, Deputy General Counsel, acted in her place for this item.

Mr. Bernard Plovnick, Senior Program Analyst, Determination of Need Program, presented the New England Rehabilitation Hospital application to the Council. He noted in part, "...We are pleased to present for your consideration an application filed by New England

Rehabilitation Hospital, an affiliate of Five Star Quality Care, Incorporated. It is a private, for-profit, 168 bed, acute rehabilitation hospital, located in Woburn. New England Rehab operates two satellite inpatient facilities, a 20-bed facility in Danvers, and a 22-bed facility in Lowell. With this application, New England Rehab seeks to relocate its Lowell satellite to another site in Lowell."

Mr. Plovnick noted that a public hearing was held in Lowell upon the request of one of the five Ten Taxpayer Groups registered with this project, the Neuro-Rehab Associates Inc. TTG, which represents the Northeast Rehabilitation Hospital network of Salem, New Hampshire, a competitor of New England Rehab for the Lowell and Merrimack Valley acute rehabilitation services market. This group testified at the public hearing, submitted written comments and addressed the Council at today meeting. [See the staff summary for summarized comments of all parties of record and a complete copy of the comments made by the Neuro Rehab Associates/Northeast Rehab Hospital Network Ten Taxpayer Group]. The other registered TTGs are Genesis Healthcare Corporation, Sunny Acres Nursing and Rehabilitation Center, Fairhaven Health Systems, Inc., and Glenwood Care & Rehabilitation Center. The staff summary notes, "All of the TTGs represent health care providers in the Lowell area, each one a competitor of NERH, D'Youville Transitional Care, and/or D'Youville Senior Care. One of the TTGs is an affiliate of Northeast Rehabilitation Hospital of Salem, N.H..."

Mr. Plovnick noted all the comments were in opposition to the transfer. Mr. Plovnick spoke about Neuro-Rehab Associates and said, "During the DoN review period, this Ten Taxpayer Group argued repeatedly for dismissal of New England Rehab's DoN on various procedural grounds. In its written comments in opposition to Staff's findings and recommendations, the TTG challenged the manner in which DoN staff applied the DoN Guidelines to the project and criticized Staff for recommending the approval of unnecessary cost to the health care system. We sharply disagree. In our response to the TTGs comments, in our memorandum to the Council, we demonstrate the extent to which our application of the DoN

Guidelines to this project has been prudent, responsible, and consistent with our limited authority."

He noted that the 1992 Guidelines that apply to this application, explicitly state that an existing provider of acute rehabilitation services may replace its existing beds on a one-for-one basis, whether or not there is need for the beds. Therefore need cannot be considered in this type of application. Mr. Plovnick noted further that there is a provision where the Guidelines suggest a certain space allocation per bed for acute rehabilitation services but continues on to state that the more important comparison is other similar facilities and that is what staff did in its analysis, looked at other similar projects and New England Rehab compared favorably like the Spaulding Rehabilitation Hospital application.

Mr. Joel Rudin, CEO, New England Rehabilitation Hospital, addressed the Council. He noted, "...The application before you is a straightforward one. We are simply requesting the Council's approval for the relocation of our existing 22 licensed Lowell beds to a new site in Lowell, 2.5 miles away. We have operated in our current location for over a decade and it has become increasingly clear that that this site is simply not sustainable for us over the long term. Our beds occupy part of one floor of the old St. Joseph's hospital in Lowell. The rest of this former acute care hospital is completely vacant, and I mean, completely vacant. Saints Medical Center historically operated numerous clinics and services in this building. Over time, these clinics and services have migrated to other locations. Other building tenants have left the building, as well, leaving New England Rehab as the only remaining health care provider at this location. In addition, over the last three years, building ownership has changed multiple times. These changes have been disruptive and have resulted in problems with the delivery of building support services. Despite these challenges, our Lowell unit has high patient satisfaction and scores high on all quality measures. This past year, our network including the Lowell unit received Gold Seal Stroke Program certification from the Joint Commission. We believe that the proposed new location for these 22 beds on a campus of D'Youville Senior Care, in addition to eliminating the

problems we encounter at our present location, provides us with the best options for continuing to render high quality acute inpatient rehabilitation services in this community. Moreover, at our new location, the Lowell unit will be more economically efficient. Our leased square footage will decrease and our operating costs will be reduced, as well. Finally, co-locating with another complementary health care provider will enable us to take advantage of clinical synergies which have been absent at our current location."

In summary he said, "As the only acute inpatient rehab provider in the City of Lowell, and its contiguous communities, our relocation is important to maintain the availability of this level of care for the residents of the Greater Lowell area."

In response to a question by Dr. Alan Woodward regarding less square footage needed in the new location, Mr. Rudin said it was due to less room needed for support services such as food service which they have to provide in the current location themselves but can purchase from their landlord D'Youville Senior Care at the new location. He further indicated that for clinical space, there will be a thousand square feet identified for inpatient therapy services and for those patients needing specialized services they will be available at their Woburn location, but this is rarely needed, like the use of the warm water therapy pool in Woburn. The rooms at the new location are a little larger than the rooms in the current location. In addition they will have 10 foot wide hall corridors instead of the 8 foot wide required in order to accommodate wheelchairs and assistive devices which most of their patients have.

Mr. John Prochilo, CEO, of Northeast Rehabilitation Hospital Network, Salem, New Hampshire, accompanied by Attorney Russell Robinson and Dr. Phil Katz were present representing the Ten Taxpayer Group. Mr. Prochilo noted in part, "...Staff acknowledges that the 1992 Rehab Guidelines are now out of date...We have to preserve our rights because our attorney believes that the Guidelines, in order to be waived, should be coming in front of the Public Health Council, and through a public process...We want to look behind the Guidelines and look at the rationale that the staff has placed forward...the first

guideline that was waived was the 60-bed minimum guideline...the issue for us is that the staff never established what the economics of the stand-alone 22-bed facility was...our next concern is the one-to-one replacement of beds...here the recommendation is to adhere the Guidelines in favor of the applicant. The staff recommends one-to-one replacement of all 22 beds because the Guidelines allow it....what happens if all 22 beds are not currently being utilized...Therefore, the cost per occupied bed, rather than the cost per bed, is really what we are looking for, to go to whether we have met the threshold to meet the spirit of the Guidelines...Staff has not explored whether or not all 22 beds are needed because the Staff has never pursued an exploration of the occupancy trends of the unit, although we have asked them to do so on at least two occasions. The applicant states that that they will be serving the same population and that they don't expect utilization to improve as a result of the relocation."

Mr. Prochilo continued, "...We have been informed that the census of the Lowell satellite ranges between five and ten patients...that doesn't surprise me because as in the Spaulding Rehabilitation Hospital, they have gone down over 200 beds to 135 beds because the number of patients going into acute rehabilitation have decreased significantly...the expense of each patient is increasing and reimbursement is remaining flat." Mr. Prochilo noted that they asked staff to request of the applicant a copy of their profit and loss statement for the Lowell location in order to insure economic feasibility. The application has a financial statement of the entire New England Rehab Hospital including satellites and outpatients. He further noted that the applicant has put in their lease for the new location, a clause allowing them to discontinue the lease if the average daily patient census is down less than twelve beds even though they have asked to transfer 22 beds.

Discussion followed by the Council. Please see verbatim transcript for complete testimony and discussion. Excerpts follow from the discussion. Dr. Cunningham asked the TTG why they are worried about the economics because the applicant assumes the risk and will lose their money if they are not feasible. Mr. Prochilo replied, "...We would argue that it is the Health Care System's money." Dr.

Rosenthal noted as an economist, she didn't understand the TTG's economic concern. Attorney for the TTG, Russell W. Robinson, Posternak, Blankstein & Lund reiterated that their concern is that the "Health care system bears the cost of these expenditures because the revenues for rehabilitation hospitals and satellite units come from reimbursement from the health care system."

Mr. Paul Lanzikos asked the TTG two questions (1) ...would the population of Lowell be better served by having or not having the current acute rehabilitation services? And (2) if the transfer is approved and the applicant establishes their new operation, would this have adverse economic impact on their Northeast Rehab Hospital? Mr. Prochilo replied that New England Rehab and Northeast Rehab Hospital are already in competition and they don't anticipate that changing and he replied further that Northeast Rehab has two outpatient facilities in Lowell and an inpatient facility in Salem, NH which is less than 15 miles away from the applicant's facility.

Staff returned to the table. Mr. Plovnick responded to the Ten Tax Payer Group's comments. He said in part. "...I don't think it is accurate to say that we waived the Guidelines. As regulators, we enforce them and we also interpret them and where the Guidelines are out of date, we do our best to interpret them...the economic feasibility issue raised was not relevant to this application. It appears in the Guidelines in the context of establishing a minimum unit size for a new facility – sixty beds for a free-standing facility. This is not a new facility and the Guidelines give an existing provider the ability to replace beds on a one-for-one basis, regardless of need. We do not look at bed need for this type of application and that was the context in which economic feasibility was stated...We certainly know and have had good evidence to support that a sixty-bed minimum is probably not feasible. Northeast Rehab Network, the TTG, is building a 33-bed freestanding satellite in Salem, NH...This is a cost savings. We didn't see that there was necessity to look at the details of the economic feasibility issue." He noted that the $3.8 million dollar Maximum Capital Expenditure, nearly half of it is comprised of the fair market value of the lease, which is accounted for but would

already be part of the operating budget of the applicant. Ms. Gorga noted the clause put in the lease by the applicant, noted earlier by the TTG, was a prudent thing for the applicant to do and further that DoN queried the landlord, who told them that if the applicant is not a success, they are not dependent on them and could absorb the loss from that rental income.

The applicant returned to the table and answered questions from the Council. Mr. Rubin indicated that there is no public money at risk with this project; that it is internally funded and noted that their average daily census has been over ten for the past three years. Mr. Rudin said in part, "...I wouldn't be before you and I would be short-lived in my role, if I wasn't prudent in terms of our expenditures in going through this application process. We have been functioning in this location successfully for eleven years. The application is a very simple one. We want to continue to provide services within the City of Lowell. We worked hard to identify an alternate site for our beds. We believe we found the best possible alternative for us, and we would like to continue providing this level of care. We are truly unique in this community. We are the only acute inpatient rehab unit provider in the City of Lowell and in each contiguous community..."

The applicant further noted that the census had declined in the industry due to certain populations using lower levels of care for single joints, hips and knees. They have more complex patients now, more neuro rehab patients which are expected to not decline but increase over the next ten years.

In terms of transportation for Lowell residents, it was noted to be challenging and that if the applicant's service closed residents would have to travel to Northeast Rehab Hospital in Salem, NH. There is no public transportation that could transport patients to Salem from Lowell; they would have to rely on a chair car for transport.

Council Member Meredith Rosenthal, made a motion to approve staff's recommendation. After consideration, upon motion made and duly seconded, it was voted unanimously [Dr. Zuckerman not present to vote] to approve Project Application No. 3-3B93 of FS

Commonwealth, LLC, d/b/a New England Rehabilitation Hospital with a Maximum Capital Expenditure of $3,801,104 (May 2010 dollars) and total approved GSF of construction of 12,355 GSF. As approved, this application provides for replacement and relocation of a 22-bed satellite unit currently located at 22 Pawtucket Street, Lowell, Ma to 981 Varnum Avenue, Lowell, MA on the campus of D'Youville Senior Care. Please see the staff summary of December 15, 2010 for the conditions attached to this approval. A staff summary and memorandum dated December 15, 2010 are attached and made a part of this record as Exhibit No. 14,967.

Notes: For the record, Dr. Barry Zuckerman left the meeting, just prior to the vote on this above application at about 11:30 a.m. Dr. John Cunningham left the meeting, right after the vote on the above application at 11:35 a.m. General Counsel Donna Levin returned to the meeting for the last docket item below at 11:40 a.m.

PRESENTATION: "PREVENTIVE HEALTH AND HEALTH SERVICES BLOCK GRANT UPDATE", BY JEWEL MULLEN, MD, MPH, MPA, DIRECTOR, BUREAU OF COMMUNITY HEALTH AND PREVENTION":

Jewel Mullen, MD, Director, Bureau of Community Health and Prevention, addressed the Council. Some excerpts from her presentation follow. "...It is a privilege for me to talk to you a bit about the Preventive Health Services Block Grant because of the excellent spectrum of work that the Department is doing under it...The Block Grant was first released in 1982 with some specific intent by Congress at that point to address particular needs in communities, especially Emergency Medical Services, Hypertension, Home Health Services, Urban Rodent Control, Community Water Fluoridation. Ten years later, Congress changed the funding and started aligning the priorities with Healthy People 2000, and then has modified things annually but in accordance with the ten year goals of Healthy People. In 1996, there was an amendment to address rape prevention and education and although that section was removed in 2000, there continues to be a set-aside for rape prevention and

sexual assault. As of now, we receive a little over 2.7 million dollars for activities funded by the Prevention Block Grant."

Dr. Mullen continued to describe the Prevention Block Grant, noting that at the Massachusetts Department of Public Health, five of our ten bureaus have funding to do work in the Block Grant: Community Health and Prevention (Asthma, Healthy Aging Initiatives, Oral Health, Sexual Assault Prevention); Environmental Health Bureau (Community Sanitation); Healthcare Safety and Quality (Emergency Medical Services); Health Information, Statistics, Research and Evaluation (Health Statistics); and Infectious Disease Prevention (Hepatitis B Prevention for Infants and Young Children).

She further noted that the Commonwealth earned the highest grade in the nation for its emergency medical system (American College of Emergency Physicians 2009 Report). The strengths acknowledged in the report include quality control and improvement systems such as its statewide trauma registry, stroke system of care, and PCI network for STEMI system of care.

Dr. Mullen noted that prevention efforts continue to have an impact throughout Massachusetts however these successes are not always instantly visible or dramatic. She quoted Commissioner Auerbach: "Much of the work of the Department is unheralded because it involves prevention and minimization of health risk – something that is difficult to quantify. The work of our dedicated staff results in the avoidance of disease and premature death and the guarantee that air, water and food are safe. The Department has hundreds of unsung heroes."

In conclusion, she recognized Elizabeth Greywolf, the Administrator of the Block Grant for the Department and said in part, "We will continue to address the national priorities, and work towards prevention and eliminating disparities for all Massachusetts residents."

NO VOTE/INFORMATION ONLY

FOLLOW-UP ACTION STEPS:

- Document financial barriers gaps in receiving health care as a first step to think about solutions (Zuckerman, Wong, Auerbach)
- No Further appeal to the OPP Waiver be reconsidered and seek comments on this at the public hearing (Cunningham, Auerbach)
- Look at Resources to communicate BPA information in different languages (Rivera to Wilkinson)
- Keep Public Health Council Informed every few months on developments with BPA Information in case further action is needed (Woodward to Wilkinson)
- Consumer Education on heating plates and bowls due to BPA (Cunningham to Wilkinson)

LIST OF DOCUMENTS PRESENTED TO THE PHC FOR THIS MEETING:

- Docket of the meeting
- Docket Item 1a: Copy of letters of meeting notices to A&F and Secretary of the Commonwealth
- Docket Item 1b: Draft Minutes of October 13, 2010
- Docket Item 2: Staff Memorandum to the Public Health Council (PHC), dated December 15, 2010 with the draft regulations on Proposed New Regulation 105 CMR 129.000, Health Insurance Open Enrollment Waivers
- Docket Item 3: Staff Memorandum to the PHC dated December 15, 2010, with the regulations (Appendix A), Chart on what other states are implementing on this matter (Appendix B) and A summary of public testimony (Appendix C)
- Docket Item 4: Staff Summary of Project Application No. 3-4937 of Eye Institute of the Merrimack Valley, Inc.
- Docket Item 5: Staff Summary of Project Application No. 3-3B93 FS Commonwealth, LLC, d/b/a New England Rehab. Hospital, and staff memorandum both dated December 15, 2010
- Docket Item 6: Copy of Powerpoint Slides on the Preventive Health and Health Services Block Grant Update"

The meeting adjourned at 11:50 a.m.

_____

John Auerbach, Chair

LMH